

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor Patent Application of:  
Harry R. Davis

Serial No.: 10/057,629

Filed: January 25, 2002

For: Use of Substituted Azetidinone  
Compounds for the Treatment of  
Sitosterolemia

Examiner: To Be Assigned

Group Art Unit: 1614

Atty. Docket No.: CV01382K

RECEIVED

INFORMATION DISCLOSURE STATEMENT

NOV 05 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TECH CENTER 1600/2900

Sir:

Pursuant to Rule 56, it is requested that the documents listed on the accompanying PTO-1449 Form be considered and made of record in the above-identified patent application. Copy(ies) of these references ☒ are attached ☐ were filed in related application U.S. Serial No(s) \_\_\_\_\_ filed \_\_\_\_\_, respectively.

(b) No fee is believed due because:

- ☐ This Information Disclosure Statement is being filed within three (3) months of the filing date of the application.
- ☐ This Information Disclosure Statement is being concurrently filed with the above-identified application.
- ☐ This Information Disclosure Statement is being concurrently filed with a Request for Continued Examination (RCE).
- ☒ This Information Disclosure Statement is being filed prior to the mailing of a first Office Action on the merits.

(c) ☐ This Information Disclosure Statement is being filed before the mailing date of any final action, notice of allowance or an action that otherwise closes prosecution; and

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or




- ☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.
- (d) ☐ This Information Disclosure Statement is being filed on or before the payment of the issue fee; and
- ☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
- ☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 19-0395, Patent Case No. CV01382K. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,  
SCHERING-PLOUGH CORPORATION

Dated: **October 28, 2003**  
SCHERING-PLOUGH CORPORATION  
Patent Department, K-6-1, 1990  
2000 Galloping Hill Road  
Kenilworth, NJ 07033-0530  
Facsimile No.: (908) 298-5388

By:

  
Name: **Ann M. Cannoni**  
Reg. No.: **35,972**  
**Attorney of Record**  
Telephone No.: (908) 298-5024

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450 ON October 28, 2003.  
(DATE OF DEPOSIT)

ANN MARIE CANNONI, REG. NO. 35,972  
(REGISTERED REPRESENTATIVE)

  
(SIGNATURE AND DATE)





FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: CV01382K	SERIAL NO.: 10/057,629
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)		APPLICANT: Harry R. Davis	
		FILING DATE: January 25, 2002	GROUP: 1614

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	5,021,461	06/04/91	Robinson et al.			
	AB	4,687,777	08/18/87	Meguro et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
	AC	WO 97/28149	08/07/97	PCT				
	AD	WO 99/22728	05/14/99	PCT				
	AE	WO 01/96347	12/20/01	PCT				
	AF	WO 02/26729	04/04/02	PCT				
	AG	WO 02/064094	08/22/02	PCT				
	AH	WO 95/35277	12/28/95	PCT				
	AI	WO 02/50027	06/27/02	PCT				
	AJ	WO 02/50060	06/27/02	PCT				
	AK	WO 02/50068	06/27/02	PCT				
	AL	WO 99/08501	02/25/99	PCT				
	AM	WO 94/26738	11/24/94	PCT				
	AN	EP 1 036 563 A1	09/20/00	EPO				
	AO	EP 0 753 298 A1	01/15/97	EPO				
	AP	FR 1103113	10/31/55	FRANCE			X (abs.)	

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AQ	Stuart B. Rosenblum et al., Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH 58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption, <i>J. Med. Chem.</i> <b>41</b> :973-980 (1998)
AR	Gilbert R. Thompson et al., Novel lipid-regulating drugs, <i>Exp. Opin. Invest. Drugs</i> <b>9</b> (11):2619-2628 (2000)
AS	T. Kosoglou et al., Coadministration of Ezetimibe and Fenofibrate Leads to Favorable Effects on Apo CIII and LDL Subfractions, <i>Atherosclerosis</i> <b>2</b> :89 (2001)
AT	Harry R. Davis et al., The Synergistic Hypocholesterolemic Activity of the Potent Cholesterol Absorption Inhibitor, Ezetimibe, in Combination With 3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase Inhibitors in Dogs, <i>Metabolism</i> <b>50</b> (10):1234-1241 (2001)
AU	Study Showed Ezetimibe Significantly Reduced Levels of LDL Cholesterol or "Bad" Cholesterol in Patients, Schering-Plough Press Release
AV	T. Kosoglou et al., Pharmacodynamic Interaction Between Fenofibrate and the Cholesterol Absorption Inhibitor Ezetimibe, <i>Atherosclerosis</i> (2):38 (2001)
AW	Remington's Pharmaceutical Sciences, 18 <sup>th</sup> ed. 1990 p. 1319, 1633-1647
AX	Baker S G et al., Treatment of homozygous familial hypercholesterolaemia with probucol, <i>South African Medical Journal</i> (1982)
AY	R. Milanese et al., Xantom E ipercolesterolemia: Prevalenza, Diagnosi e Terapia, <i>Chron. Derm.</i> <b>455-61</b> (1990)

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.